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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/545,193

05/17/2006

Steven Brian Gendreau

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EXAMINER

YAO, LEI

ART UNIT

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/545,193	Applicant(s) GENDREAU ET AL.	
	Examiner LEI YAO	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, 16, 17, drawn to an in vitro method of identifying a candidate APC and Axin pathway modulating agent comprising providing DYRK polypeptide, contacting, detecting the test agent in the assay system.

Group 2, claim(s) 1, 11, 12, 16, 18, 19, drawn to an in vivo method of identifying APC and Axin pathway modulating agent comprising providing DYRK polypeptide, contacting, detecting the test agent and further comprising administering the test agent and determining the defective in beta catenin protein function in mouse model.

Group 3, claim(s) 1,8-10, drawn to an in vitro method of identifying a candidate APC and Axin pathway modulating agent comprising providing DYRK nucleic acid, contacting, detecting the test agent in the assay system, wherein the modulator is an antisense oligomer.

Group 4, claim(s) 13,15, 20, 22, drawn to an in vitro method of modulating a APC and Axin pathway of a cell comprising contacting a cell defective in beta catenin (protein) function with a candidate modulator that binds to DYRK polypeptide

Group 5 claim(s) 13-15, 20-22, drawn to claim(s) 13 and 15, drawn to an in vivo method of modulating a APC and Axin pathway of a cell comprising administering to an animal having a disease from the defective in beta catenin function with a candidate modulator that binds to DYRK polypeptide.

Group 6, claim(s) 23-25, drawn to a method of diagnosing a disease in a patient comprising obtaining, contacting, determining a biological with a probe (nucleotides) for the DYRK expression for determining likelihood of cancer.

According to PCT rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groupings are directed to in vitro or in vivo method involved in beta catenin expression or function but each group has ad different special technical feature not sheared by the remaining groups. Groups 1 and 2 are directed to in vitro and in vivo method of identifying a candidate beta catenin pathway modulating agent which has the

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special technical feature of in vitro contacting cell (group 1) with and in vivo administering (group 2) the test compound for detecting protein, not shared by any of the remaining groups or each other. Group 3 is directed to in vitro method of identifying a candidate beta modulator of antisense nucleic acid, which has the special technical feature of antisense, not sheared by any of the remaining groups. Group 4 are 5 are directed to in vitro or in vivo method of modulating candidate beta pathway, which has the special technical feature in vitro contacting with and in vivo administering the modulator, not sheared by any of the remaining groups or each other. Group 6 is directed to method of diagnosing a disease in a patient with a probe for expression of the UP expression for determining the disease, which has the special technical feature of the gene expression detecting with probe, not sheared by any of the remaining groups.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. small molecule, antibody, nucleic acid modulator
- b. phosphorylase assay, apoptosis assay, cell proliferation assay, angiogenesis assay, hypoxic induction assay, binding assay.
- c. cancer listed in table 1.

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The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

If Applicant elects any invention from group 1, 2, 4-5, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from a) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, elect antibody.

If Applicant elects invention group 1, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, an assay method, from b) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, cell proliferation assay.

If Applicant elects invention group 6, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, a cancer, from c), listed in table 1, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, breast cancer.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643